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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,326	12/22/2000	Koh Sato	04853.0052	9287

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 01/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/720,326	<b>Applicant(s)</b> SATO ET AL	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1, 4, 6, 9-21, 33 and 43-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1, 4, 6, 9-21, 33 and 43-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

Claims 1, 13 and 33 have been amended. Claims 33-42 have been canceled. Claims 43-53 have been added. Claims 1, 4, 6, 9-21, 33 and 43-53 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a previous action.

Claims 1, 4, 6, 9-21, 33 and 43-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 13 and 33 have presumable been amended to reflect the decrease in blood calcium level as indicated in one of the Figures. New claims 47, 48 and 50-53 require specific reductions in ionized calcium levels to be reached by 4 hours. However, the amendment does not address the significance of the Y axis in the figures which is labeled to be variation in ionized blood calcium level in nmol/L. Because of this labeling, one of skill in the art would conclude that -0.3 is a drop of 0.3 nmol/L from the starting value of ionized calcium which would have no significance for an overall percentage decrease unless the starting concentration of ionized calcium were disclosed. Thus, the instant amendments are not supported by the specification as filed because it cannot be determined what the percentage of decrease is without knowing the starting concentrations. New claims 43-53 specify various percentages of decreased ionized calcium maintained over at least 3 days and at least 5 days which is not supported by the originally filed specification which does not contemplate intervals of time corresponding to at least 3 days and at least 5 days. One of skill in the art would reasonable conclude that applicant was not in possession of the claimed invention.

Claims 1, 4, 9-15, 17-21, 33 and 43-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of treatment using the antibody deposited under ATCC No. 5631, does not reasonably provide enablement for any other antibody which binds to the PHTrP and inhibits the binding between PHTrP and the receptor for

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PHTrP. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims have been amended to require a specific decrease in blood ionized calcium level over specific periods of time. The specification has provided the humanized antibody deposited under ATCC No. 5631 which functions as claimed. It is unclear if any other antibody which bound to PHTrP and inhibited the binding of PHTrP to the receptor thereof would exhibit the same rate of decrease in ionized blood calcium over time. It is noted that inhibition of PHTrP binding to the receptor can occur through physical binding of the antibody to PHTrP on the entire epitope which would contact the receptor, or on an epitope which would partially contact the receptor, or on an epitope near to the epitope which could contact the receptor and thus impede the physical contact of PHTrP with the receptor. However, it is unclear if such a genus of antibodies would exhibit the rate of decrease in ionized calcium levels as now claimed because the affinity of the PHTrP-antibody complex for the receptor would vary as a function of the particular epitope on PHTrP bound by the anti-PHTrP antibody. Because the specification provides only a single antibody having these characteristics, one of skill in the art would be subject to undue experimentation in order to practice the claimed method with other antibodies which inhibit the binding of PHTrP to the receptor thereof.

Claims 1, 4, 6, 9-21, 33 and 43-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,903,194. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the '194 patent would inherently comprise the characteristics of the instant method claims when administered to a subject in need thereof.

All other rejections and objections are withdrawn in light of applicants amendments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

12/27/2005

  
KAREN A. CANELLA PH.D.  
PRIMARY EXAMINER